

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

400 R Street, Room 369  
Sacramento, California 95811  
(916) 326-3660 FAX (916) 322-2512



**AGENDA**  
**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)**  
**CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY**

**400 R Street, Room 300**  
**Sacramento, CA 95811**

**Friday, December 5, 2008**  
**8:30 am – 5:00 pm**

**A. General Items**

1. Administrator's Report
  - a. PRIM&ER Conference
  - b. Recruitment of members – Bulletin Update
  - c. Request for Primary Reviewer to retain copy of full committee protocols
  - d. Website instructions/forms changes
    1. HIPAA
    2. Bill of Rights
    3. SB 13
    4. Death Data
2. Office of Human Research Protections engagement in research guidance
3. Howard Harris being honored by Urban League on Dec. 11th
3. Unanticipated Event  
Project No. 01-08-12  
Project Title: "Adult Testicular Cancer Lifestyle and Blood Specimen (ATLAS) Study"  
Principal Investigator: Steven Schwartz, PhD  
Fred Hutchinson Cancer Research Center  
Seattle, WA

**B. Approval of Minutes**

August 1, 2008 and October 3, 2008

**C. Continuing Projects Calendar - Previously approved projects requiring full committee reapproval****Projects with major revisions and requiring periodic review**

1. Project No. 03-10-01 (Reviewer – Galbraith/Dickey)  
Project Title: "Measured Parameters in MidPregnancy Blood Specimens and Risk of Birth Defects"  
Principal Investigator: Gary Shaw, DrPH  
March of Dimes  
Oakland, CA

2. Project No. 02-08-03 (Reviewer – Mihordin/Dickey)  
Project Title: “Genetic Susceptibility to Hypospadias”  
Principal Investigator: Suzan Carmichael, PhD  
March of Dimes  
Oakland, CA
3. Project No. 07-12-09 (Reviewer – Galbraith)  
Project Title: “Research in Language and Cognitive Development”  
Principal Investigator: Catherine Sandhofer, PhD  
UCLA  
Los Angeles, CA

**Projects requiring periodic review only – (including moderate risk)**  
**Some projects listed may have been approved by expedited review prior to this meeting and will not be reviewed by the full committee.**

1. Project No. 05-12-52 (Reviewer - Murphy)  
Project Title: “Impact of Violence During Pregnancy on Birth Outcomes”  
Principal Investigator: Anna Aizer, PhD, MS  
Brown University  
Providence, RI
2. Project No. 06-12-51 (Reviewer - Harris)  
Project Title: “Validation of Selected Items in the 2005 Patient Discharge Data Set”  
Principal Investigator: Andrew Bindman, MD  
UCSF  
San Francisco, CA
3. Project No. 05-12-53 (Reviewer - Ruiz)  
Project Title: “The Effect of Hospitals on racial Disparity in Coronary Artery Bypass Graft Surgery Outcomes”  
Principal Investigator: Andrew Bindman, MD  
UCSF  
San Francisco, CA
4. Project No. 05-12-59 (Reviewer - Harris)  
Project Title: “Perinatal Profiles”  
Principal Investigator: Ralph Catalano, PhD  
UC Berkeley  
Berkeley, CA
5. Project No. 02-12-15 (Reviewer - Harris)  
Project Title: “Epidemiology of Lead Poisoning Due to In-Utero Exposure Among Neonates”  
Principal Investigator: Joseph Courtney, PhD  
CDPH

Richmond, CA

6. Project No. 03-12-01 (Reviewer - Murphy)  
Project Title: "Father Involvement Initiative"  
Principal Investigator: Philip Cowan, PhD  
UC Berkeley  
Kensington, CA
7. Project No. 01-12-04 (Reviewer - Murphy)  
Project Title: "Use of Linked Data Bases to Assess Selected Quality Indicators  
for Maternal and Infant Health"  
Principal Investigator: Lisa Croen, PhD  
Kaiser Permanente  
Oakland, CA
8. Project No. 03-12-54 (Reviewer - Murphy)  
Project Title: "Delayed Health Care Among the Near-Elderly"  
Principal Investigator: Carlos Dobkin, PhD  
UC Santa Cruz  
Santa Cruz, CA
9. Project No. 07-12-54 (Reviewer - Galbraith)  
Project Title: "The Impact of Medicare on Emergency Department and Hospital  
Treatment"  
Principal Investigator: Carlos Dobkin, PhD  
UC Santa Cruz  
Santa Cruz, CA
10. Project No. 03-12-51 (Reviewer - Kirkish)  
Project Title: "The Productivity of Medi-Cal Prescription Drug Spending"  
Principal Investigator: Mark Duggan, PhD, MS  
University of Maryland  
College Park, MD
11. Project No. 07-12-05 (Reviewer - Ward)  
Project Title: "A Multi-site Evaluation of a State-funded Peer-based  
HIV Prevention Program for Injection Drug Users and  
Satellite Syringe Exchanges in California"  
Principal Investigator: Valorie Eckert, MPH  
California Department of Public Health  
Sacramento, CA
12. Project No. 06-12-52 (Reviewer - Harris)  
Project Title: "Utilization of Antidepressants in Children and Adolescents < 18  
Years of Age"  
Principal Investigator: Patrick Finley, Pharm.D  
UCSF

San Francisco, CA

13. Project No. 06-10-03 (Reviewer - Galbraith)  
Project Title: "Brief Interventions for Problem Gamblers: Evaluating a Self-Help Workbook"  
Principal Investigator: Timothy Fong, MD  
UCLA  
Los Angeles, CA
14. Project No. 04-12-02 (Reviewer - Kirkish)  
Project Title: "Pediatric Endurance Development and Limb Strengthening for Children with Cerebral Palsy"  
Principal Investigator: Eileen Fowler, PhD, PT  
UCLA  
Los Angeles, CA
15. Project No. 03-12-55 (Reviewer - Snipes)  
Project Title: "Antecedent Pregnancy Outcomes of Children with Cerebral Palsy and other Neurologic Diseases"  
Principal Investigator: William Gilbert, MD  
UC Davis  
Sacramento, CA
16. Project No. 07-12-08 (Reviewer – Mihordin)  
Project Title: "Ultrafine Particle Exposure and Respiratory Outcomes among Bicycle Commuters"  
Principal Investigator: Susan Gilbreath, PhD  
Air Resources Board  
Sacramento, CA
17. Project No. 07-12-59 (Reviewer - Snipes)  
Project Title: "Southern California Wildfires and Adverse Birth Outcomes"  
Principal Investigator: Frank Gilliland, MD, PhD  
USC  
Los Angeles, CA
18. Project No. 03-12-61 (Reviewer - Murphy)  
Project Title: "Rate and Risk Factors for Abacavir Re-Exposure after Provider Diagnosed Hypersensitivity Reaction"  
Principal Investigator: Robert Gross, MD  
University of Pennsylvania  
Philadelphia, PA
19. Project No. 03-12-52 (Reviewer - Murphy)  
Project Title: "Occurrence and Distribution of Autism in California"  
Principal Investigator: Irva Hertz-Picciotto, PhD  
UC Davis  
Davis, CA

20. Project No. 07-12-06 (Reviewer – Galbraith)  
Project Title: “Brain Mechanisms of Visual Development”  
Principal Investigator: Scott Johnson, PhD  
UCLA  
Los Angeles, CA
21. Project No. 07-12-58 (Reviewer - Ruiz)  
Project Title: “Disparities in Treatment and Survival of Gastrointestinal Malignancies Among Asian-Americans in Southern California”  
Principal Investigator: Joseph Kim, MD  
City of Hope  
Duarte, CA
22. Project No. 07-12-01 (Reviewers – Snipes-English, Dinis-Spanish)  
Project Title: “Social Climate Evaluation of California’s My Strength Campaign: Phase Two”  
Principal Investigator: Mina Lai, MPH  
California Department of Public Health  
Sacramento, CA
23. Project No. 06-12-58 (Reviewer - Dinis)  
Project Title: “Study of the Role of Cytokines in the Pathogenesis of Influenza and other Respiratory Viruses”  
Principal Investigator: Janice Louie, MD, MPH  
CDPH  
Richmond, CA
24. Project No. 03-12-57 (Reviewer - Ruiz)  
Project Title: “Medication Persistence and the Costs of Noncompliance in a Medi-Cal Population”  
Principal Investigator: Michael Nichol, PhD  
USC  
Los Angeles, CA
25. Project No. 01-12-11 (Reviewer - Murphy)  
Project Title: “Survey of Proportion of Voluntary HIV Testing and Assessment of HIV Testing Method Preferences Among Incoming Prisoners at the California Medical Facility (CMF)”  
Principal Investigator: Juan Ruiz, MD, DrPH, MPH  
CDPH  
Sacramento, CA
26. Project No.06-12-06 (Reviewer – Murphy)  
Project Title: “Positive Transitions”  
Principal Investigator: Barry Zack, MPH  
Centerforce, Inc.  
San Rafael, CA

27. Project No. 07-12-56 (Reviewer - Ward)  
Project Title: "Pooled Analysis of Very Low Birth Weight and Childhood Cancer"  
Principal Investigator: Peggy Reynolds, PhD  
Northern California Cancer Center  
Berkeley, CA
28. Project No. 98-12-09 (Reviewer - Mihordin)  
Project Title: "Regional Variations in Breast Cancer Rates in California"  
Principal Investigator: Peggy Reynolds, PhD  
Northern California Cancer Center  
Berkeley, CA
29. Project No. 93-12-01 (Reviewer - Murphy)  
Project Title: "Regionalization, Market Forces, and Neonatal Mortality"  
Principal Investigator: Ciaran Phibbs, PhD  
Health Economics Resource Center, VA  
Menlo Park, CA
30. Project No. 98-12-05 (Reviewer - Mihordin)  
Project Title: "Candidate Genes and Biologic Markers, Potential Interacting Exogenous Factors, and Conotruncal Heart Malformations and Limb Anomalies"  
Principal Investigator: Gary Shaw, DrPH  
March of Dimes  
Oakland, CA
31. Project No. 98-12-04 (Reviewer - Mihordin)  
Project Title: "Ultra-Micro Immunoassay of Newborn Blood Spots for Children in the 1988-1989 Study of Gastroschisis"  
Principal Investigator: Gary Shaw, DrPH  
March of Dimes  
Oakland, CA
32. Project No. 06-12-55 (Reviewer - Murphy)  
Project Title: "AWARE Data Project - Antibiotic Prescribing Study"  
Principal Investigator: Rita Smith, MD  
University of Washington  
Seattle, WA

**Projects with revisions only**

**Some projects listed may have been approved by expedited review prior to this meeting and will not be reviewed by the full committee.**

1. Project No. 03-02-06 (Reviewer – Lowe)  
Project Title: "Survey of Body Burdens in California Communities"  
Principal Investigator: Kim Hooper, PhD  
Department of Toxic Substances Control  
Berkeley, CA

2. Project No. 07-02-02 (Reviewer – Ward)  
Project Title: “Markers for Autism Risk in Babies-Learning Early Signs (M.A.R.B.L.E.S.)”  
Principal Investigator: Irva Hertz-Picciotto, PhD  
UCD  
Davis, CA

**D. Second Review Calendar – Projects not previously approved that require full committee review**

**E. New Projects Calendar**  
**New Projects - Full Committee Review Required**

1. Project No. 08-12-01 (Reviewers – Lowe)  
Project Title: “2009 California Children’s Healthy Eating and Exercise Practices Survey”  
Principal Investigator: Susan Foerster, MPH, RD  
CDPH  
Sacramento, CA
2. Project No. 08-12-02 (Reviewer – Kirkish)  
Project Title: “Early Autism Risk Longitudinal Investigation (EARLI)”  
Principal Investigator: Irva Hertz-Picciotto, PhD  
UCD  
Davis, CA
3. Project No. 08-12-03 (Reviewer – Ruiz, English and Spanish)  
Project Title: “California Youth Risk Behavior Survey”  
Principal Investigator: Marta Induni, PhD  
CDPH  
Sacramento, CA
4. Project No. 08-12-04 (Reviewer – Mihordin)  
Project Title: “Consumption of Unpasteurized Milk and Unpasteurized Milk Products: Knowledge, Attitudes, and Behaviors among a Del Norte County Population with Historically High Rates of Unpasteurized Milk Consumption”  
Principal Investigator: Amy Karon, DMV, MPH  
CDPH  
Richmond, CA
5. Project No. 08-10-61 (Reviewer –Ward)  
Project Title: “Kaiser Permanente Northern California Family Linkage Project”  
Principal Investigator: Neil Risch, PhD  
Kaiser Permanente  
Oakland, CA

6. Project No. 08-12-05 (Reviewer –Murphy)  
Project Title: “The Development of Socio-Emotional Behavior and Associated Brain Development”  
Principal Investigator: Nim Tottenham, PhD  
UCLA  
Los Angeles, CA
7. Project No. 08-12-06 (Reviewer –Harris)  
Project Title: “Children’s Development of Grammatical Rules”  
Principal Investigator: Nina Hyams, PhD  
UCLA  
Los Angeles, CA
8. Project No. 08-12-07 (Reviewer –Kirkish)  
Project Title: “VBDS Stormwater BMP Survey”  
Principal Investigator: Justin Harbison, MS  
CDPH  
Ontario, CA
9. Project No. 08-12-08 (Reviewer –Murphy)  
Project Title: “Validation of the Revised COJAC Screening Tool for Co-Occurring Disorders”  
Principal Investigator: Martha Jessup, RN, PhD  
UCSF  
San Francisco, CA

**New Projects - Expedited Review Requested, but which may require full committee review. Some projects listed may have been approved by expedited review prior to this meeting and will not be reviewed by the full committee.**

1. Project No. 08-12-63 (Reviewer - Mihordin)\_  
Project Title: “The Impact of E-Prescribing in Northern Sierra Rural Health Network”  
Principal Investigator: Kevin Boesen, PharmD  
University of Arizona  
Tucson, AZ
2. Project No. 08-12-58 (Reviewer - Mihordin)\_  
Project Title: “Pilot Study of Trends and Risks in Gestational Diabetes”  
Principal Investigator: Assiamira Ferrara, MD, PhD  
Kaiser Permanente  
Oakland, CA
3. Project No. 08-12-60 (Reviewer - Snipes)\_  
Project Title: “Mental Health Services and Client Outcomes”  
Principal Investigator: Wei-Chin Hwang, Phd, MA



Claremont McKenna College  
Claremont, CA

4. Project No. 08-12-56 (Reviewer - Ward)\_  
Project Title: "Replication of Draper Study of Leukemia, Brain Tumors and Distance to Power Lines in California"  
Principal Investigator: Leeka Kheifets, PhD, MA  
UCLA  
Los Angeles, CA
5. Project No. 08-12-62 (Reviewer - Snipes)\_  
Project Title: "The Effects of Choice Context on Decision-Making: An Application to Voter Fatigue"  
Principal Investigator: Scott Nicholson  
Stanford University  
Stanford, CA
6. Project No. 08-12-59 (Reviewer - Snipes)\_  
Project Title: "Cord Morality Risk Adjustment with Present on Admission Diagnoses"  
Principal Investigator: George J. Stukenborg, PhD, MA  
University of Virginia  
Charlottesville, VA
7. Project No. 08-12-61 (Reviewer - Ward)\_  
Project Title: "Medi-Cal Spending on Psychotropic Drugs and Its Effect on Health Outcomes and Expenditures"  
Principal Investigator: Jangho Yoon, PhD, MSPH  
DHCS  
Sacramento, CA

**F. Projects with Request for CPHS to Rely on Another Institutional Review Board (IRB) (CPHS will decide on whether to rely on another IRB for approval of these projects)**

**G. Projects with Reported Adverse Events (CPHS will decide if any action on these projects is necessary)**

**H. Exemption Request**

**I. Next Meeting**

The next CPHS meeting is scheduled for February 6, 2009 in Sacramento.

**J. Adjournment**

**NOTE: Action may be taken on any items listed in this agenda.**

**To request any background materials prior to the meeting please contact [cphs-mail@oshpd.ca.gov](mailto:cphs-mail@oshpd.ca.gov).**

Pursuant to the Americans with Disabilities Act, the meeting is accessible to people with mobility impairments. Please contact CPHS, [cphs-mail@oshpd.ca.gov](mailto:cphs-mail@oshpd.ca.gov) or 916-326-3660, at least five working days in advance of the meeting to make arrangements for persons who require additional reasonable accommodations or have special needs. CPHS will ensure that it makes every effort to fulfill the request.

California Health and Human Services Agency  
Committee for the Protection of Human Subjects  
400 R Street, Room 369  
Sacramento, CA 95811  
Phone: (916) 326-3660  
Fax: (916) 322-2512  
Roxana Killian, LCSW  
Administrator  
[rkillian@oshpd.ca.gov](mailto:rkillian@oshpd.ca.gov)  
Joan Mock  
Assistant Administrator  
[jmock@oshpd.ca.gov](mailto:jmock@oshpd.ca.gov)  
CPHS website  
[www.oshpd.ca.gov/boards/cphs](http://www.oshpd.ca.gov/boards/cphs)